



John Elias Baldacci
Governor

Maine Department of Health and Human Services

Office of MaineCare Services
442 Civic Center Drive
11 State House Station
Augusta, ME 04333-0011

Brenda Harvey
Commissioner

J. Michael Hall
Director

DATE: November 7, 2006

TO: Interested Parties

FROM: J. Michael Hall, Director, Office of MaineCare Services

SUBJECT: Proposed Rule: Maine State Services Manual, Chapter 104, Sections 2, 3 and 4: Maine Drugs for the Elderly Benefit, Maine Rx Plus and Maine Part D Wrap Benefits

This letter gives notice of a proposed rule: Maine State Services Manual, Chapter 104, Sections 2, 3 and 4: Maine Drugs for the Elderly Benefit, Maine Rx Plus and Maine Part D Wrap Benefits.

The most significant change in the proposed rules is a modification of the Rural Dispensing Fee Payment (formerly known as the Maine Retail Pharmacy Provider Incentive Payment). The incentive is being revised to mirror the CMS-approved language developed for the State Medicaid (i.e., MaineCare) Pharmacy Benefit and applies to both the Maine Rx Plus and Drugs for the Elderly Benefits. The only proposed changes to the Part D Wrap Benefit are updates to the co-payment amounts outlined in Appendix A, and the inclusion of dual eligible members who are co-pay exempt under Chapter 1, Section 1.09-2 of the MaineCare Benefits Manual.

Rules and related rulemaking documents may be reviewed at and printed from the Office of MaineCare Services website at http://www.state.me.us/bms/rules/gen_rules_policies.htm or, for a fee, interested parties may request a paper copy of rules by calling 207-287-9368. For those who are deaf or hard of hearing and have a TTY machine, the TTY number is 1-800-423-4331.

A concise summary of the proposed rule is provided in the Notice of Proposed Rulemaking. This notice also provides information regarding the rule-making process. Please address all comments to the agency contact person identified in the Notice of Proposed Rulemaking.

Our vision is Maine people living safe, healthy and productive lives.

Notice of Agency Rule-making Proposal

AGENCY: Department of Health and Human Services, Office of MaineCare Services

RULE TITLE OR SUBJECT: Maine State Services Manual, Chapter 104, Sections 2, 3 and 4: Maine Drugs for the Elderly Benefit, Maine Rx Plus and Maine Part D Wrap Benefits

PROPOSED RULE NUMBER:

CONCISE SUMMARY: The most significant change in the proposed rules is a modification of the Rural Dispensing Fee Payment (formerly known as the Maine Retail Pharmacy Provider Incentive Payment). The incentive is being revised to mirror the CMS-approved language developed for the State Medicaid (i.e., MaineCare) Pharmacy Benefit and applies to both the Maine Rx Plus and Drugs for the Elderly Benefits. The only proposed changes to the Part D Wrap Benefit are updates to the co-payment amounts outlined in Appendix A, and the inclusion of dual eligible members who are co-pay exempt under Chapter 1, Section 1.09-2 of the MaineCare Benefits Manual.

SEE http://www.state.me.us/bms/rules/gen_rules_policies.htm **for rules and related rulemaking documents.**

THIS RULE WILL ☐ **WILL NOT** ☒ **HAVE A FISCAL IMPACT ON MUNICIPALITIES.**

STATUTORY AUTHORITY: 22 M.R.S.A. §§42, 3173 and 254-D, PL 2003, ch. 673, §FFF-3

PUBLIC HEARING:

Date: December 11, 2006 at 3:00 PM
Location: Conference Room 1A
Department of Health and Human Services
442 Civic Center Drive
Augusta, ME 04330

Any interested party requiring special arrangements to attend the hearing must contact the agency person listed below before December 5, 2006.

DEADLINE FOR COMMENTS: Comments must be received by midnight December 21, 2006.

AGENCY CONTACT PERSON: Scott Goulette, Comprehensive Health Planner
AGENCY NAME: Office of MaineCare Services
ADDRESS: 442 Civic Center Drive
11 State House Station
Augusta, Maine 04333-0011

TELEPHONE: 207-287-9370 **FAX:** (207) 287-9369 **TTY:** 1-800-423-4331 or 207-287-1828 (Deaf or Hard of Hearing)

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2.01 **AUTHORITY**

The Maine Drugs for the Elderly Benefit, also referred to as the Maine Low Cost Drugs for the Elderly or Disabled (DEL) Benefit, is authorized by, and these regulations are issued under, the authority of 22 M.R.S.A. §254-D(7). The Commissioner of the Department of Health and Human Services has delegated the responsibility for administration of the Benefit to the Office of MaineCare Services.

2.02 **DEFINITIONS**

- 2.02-1 **Authorized Representative** refers to the Department's authority pursuant to 22 M.R.S.A. § 254-D to enroll and reenroll DEL participants into a Medicare Part D plan, apply for Medicare Part D benefits and subsidies on their behalf, and at the Department's discretion, file exceptions and appeals on behalf of participants. The Department may also identify a designee for this function.
- 2.02-2 **Beneficiary under Medicare Part D** means a person who is eligible for and enrolled in a Medicare Part D plan.
- 2.02-3 **Brand Name Drug** is defined as a single-source drug, a cross-licensed drug, or an innovator drug.
- 2.02-4 **Coverage Gap (donut hole)** is the portion of the standard Medicare Part D benefit where the Part D plan provides no coverage and the enrollee pays 100% of the prescription after the deductible is met.
- 2.02-5 **Covered Drug** is a drug for which the Department reimburses under the DEL Benefit. See Subsection 2.05 of this Section.
- 2.02-6 **DEL Rebate Agreement** is an agreement between the Department and a drugmanufacturer that provides that the drug manufacturer will make rebate payments for both the basic and supplemental components of the Benefit.
- 2.02-7 **Drug Utilization Review (DUR)** means a process designed to ensure that prescriptions are appropriate, medically necessary, cost-effective, and not likely to result in adverse medical results.
- 2.02-8 **Drug Utilization Review Committee (DUR Committee)** means an advisory committee to the Department of Health and Human Services for the MaineCare Benefit and DEL Benefit, comprised of physicians and pharmacists who are licensed to prescribe or dispense drugs in Maine. The DUR Committee conducts drug utilization review for the Department.
- 2.02-9 **Generic Drugs** are drugs other than those defined as brand-name drugs.

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2.02 **DEFINITIONS** (cont.)

- 2.02-10 **Mail Order Pharmacy** is a pharmacy provider that dispenses prescription medications by U.S. mail or private carrier. Mail order pharmacies must have a NABP (National Association of Boards of Pharmacy) provider number uniquely identifying the provider as a mail order pharmacy for purposes of billing. Mail order pharmacies must be licensed by the Maine Board of Pharmacy, enrolled as Medicare and MaineCare providers, and be operating under contract with the Department. Mail order pharmacies must dispense prescription medications from within the United States. Mail order pharmacies must process claims through the State's electronic claims processing system to the standards required by the Department.
- 2.02-11 **MaineCare Benefits Manual (MBM)** is the MaineCare policy set forth in Department of Health and Human Services, 10-144, Chapter 101, MaineCare Benefits Manual.
- 2.02-12 **MaineCare Member** means a person who receives benefits under the MaineCare Program.
- 2.02-13 **Maine Maximum Allowable Cost (MMAC)** is the maximum reimbursement amount that is established by the Maine Department of Health and Human Services for certain multiple source drugs.
- 2.02-14 **Medicare Part D** means the prescription drug benefit program provided under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173.
- 2.02-15 **Medicare Part D Excluded Drugs** are those drugs not covered by MedicarePart D pursuant to Title XIX, Section 1927 of the Social Security Act [42 U.S.C. § 1396r-8], which the Department will continue to reimburse if otherwise covered under this Section. The Department will post a complete list of these covered drugs on its designated website, and the list will include but not be limited to the following categories of drugs: over the counter drugs, certain weight loss drugs, agents when used for the symptomatic treatment of cough and cold, vitamins/minerals, outpatient drugs for which associated tests or monitoring must be purchased exclusively from manufacturers, barbiturates, and benzodiazepines.
- 2.02-16 **Medi-Span** is a nationally recognized drug database. The Department uses this database to determine which drugs are defined as brand-name (single-source, cross-licensed or innovator) or generic (multiple-source) drugs for the purposes of calculating reimbursement.

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2.02 **DEFINITIONS** (cont.)

2.02-17 **Metropolitan Statistical Area (MSA)** is a federal standardized designation using postal zip codes to define rural areas. The Department will define rural by applying MSA/Non-MSA designation to the zip code of the member's residence.

2.02-4718 **National Drug Code (NDC)** is a universal drug coding system for human drugs established by the Federal Food and Drug Administration, as set forth in 21 C.F.R. § 207. The FDA assigns each drug a unique identification number specifying the labeler/vendor, product, and package.

2.02-4819 **Non-Preferred Drugs** are covered drugs that are not preferred drugs.

2.02-4920 **OBRA 90** is the Omnibus Budget Reconciliation Act of 1990 as amended.

2.02-2021 **Over-The-Counter Drug (OTC)** is a drug that can be purchased without a prescription.

2.02-2422 **Participant** is an individual who is eligible for and is receiving the DEL Benefit.

2.02-2223 **Pharmacy Provider** is a corporation, association, partnership, or individual that either provides pharmacy services pursuant to a provider agreement with MaineCare or is related by ownership or control to an entity that provides MaineCare or DEL Benefit services, and is also a Medicare pharmacy provider.

2.02-2324 **Preferred Drugs** are covered drugs that are clinically efficacious and which have a lower therapeutic category as determined by the Department after reviewing the recommendation of the Drug Utilization Review Committee.

2.02-2425 **Preferred Drug List (PDL)** is a listing of covered drugs setting forth such information as their status as preferred or non-preferred, whether prior authorization may be required, step order, and any other information as determined by the Department to be helpful to participants, pharmacists, prescribers and other interested parties.

2.02-2526 **Retail Pharmacy** is a pharmacy that possesses a valid outpatient pharmacy license issued by the Board of Pharmacy, accepts Medicare assignment, and which serves DEL participants.

2.02-2627 **Telepharmacy** is a method of delivering prescriptions dispensed by a pharmacist to a remote site. Pharmacies using telepharmacy delivery of prescriptions must follow all applicable State and Federal regulations and

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2.02 **DEFINITIONS** (cont.)

Maine State Board of Pharmacy rules, including using staff qualified to deliver prescriptions through telepharmacy.

2.02-~~27~~28 **Therapeutic Category** is a grouping of drugs by comparable therapeutic effect, as determined by the Department.

2.02-~~28~~29 **Usual & Customary Charge** is the amount a pharmacy charges to individuals for prescription drugs for which those individuals do not have insurance coverage.

2.03 **ELIGIBILITY**

An individual is eligible to receive services as set forth in this Section if he or she meets the eligibility requirements established in 10-144 C.M.R. Chapter 333. Some participants may have restrictions on the type and amount of benefits they are eligible to receive under this Section.

2.04 **PARTICIPATION IN MEDICARE PART D**

Participants must exhaust other pharmacy benefits including Medicare Part D and MaineCare before using DEL benefits under this Section.

2.04-1 Authorized Representative

The Department may act as an authorized representative for or appoint a designee to act as an authorized representative for participants who are dually eligible for DEL and Medicare Part D.

As an authorized representative, the Department may:

- a. deem eligible and enroll and reenroll participants in a Medicare Part D plan;
- b. apply for Medicare Part D benefits and subsidies on behalf of participants;
- c. establish rules by which participants may opt out of participation in Medicare Part D; and
- d. at its discretion, file exceptions and appeals pertaining to Medicare Part D eligibility or benefits on behalf of participants.

2.04-2 Participants Dually Eligible for Medicare Part D

For participants who are eligible for Medicare Part D, the Department may provide coverage of drugs excluded by Medicare Part D to the same extent that coverage is available to participants who are not eligible for Medicare Part D.

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2.05 **REQUIREMENTS FOR PHARMACY PARTICIPATION IN DEL**

A pharmacy that wishes to submit claims for payment under the Drugs for the Elderly Benefit must:

1. Comply with all provider and administrative process requirements set forth in Chapter 104, Section 1; and
2. Be enrolled as a MaineCare pharmacy provider.

The Department may issue a request for proposals from labelers or manufacturers and issue a contract for the provision of generic drugs. Participating providers may be required by the Department to obtain a generic drug from labelers or manufacturers with which the Department contracts. The Department will notify providers and give instructions for compliance with this provision.

2.06 **BENEFITS**

Only those drugs of manufacturers that have both a valid rebate agreement with the federal government pursuant to 42 U.S.C. § 1396r-8 and a DEL Rebate Agreement are covered in the DEL Benefit. A prescription drug of a manufacturer that does not enter into an agreement pursuant to this paragraph is reimbursable only if the Department determines the prescription drug is essential. In addition, drugs may be subject to prior authorization and the step order as set forth in this Section. The Department may refuse coverage for a drug when the prescriber cannot demonstrate medical necessity.

2.06-1 **Basic Benefit**

A. Covered Drugs

1. Prescription Drugs

The Basic benefit covers brand-name and generic drugs when administered for the following conditions and illnesses: heart disease, diabetes, high blood pressure, arthritis, chronic lung disease (including emphysema and asthma), anticoagulation, hyperlipidemia (high cholesterol), incontinence, thyroid disease, osteoporosis (bone density loss), Parkinson's disease, glaucoma, and multiple sclerosis/amyotrophic lateral sclerosis (Lou Gehrig's Disease).

2. Over-The-Counter Drugs

Some over-the-counter drugs are covered in the DEL Benefit when the Department determines that they are both cost-effective and that they have a National Drug

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2.06 **BENEFITS** (cont.)

Code (NDC) number. These drugs will be approved only when the prescriber can demonstrate, with appropriate medical justification, that the use of these drugs is medically necessary. The Department may exclude from coverage drugs that are equivalent to drugs that are available over-the-counter.

3. Benefits for Medicare Part D Eligible Beneficiaries. The Department will continue to cover Medicare Part D Excluded Drugs for eligible participants so long as those drugs are covered for other DEL participants. The Department will post a complete list of these drugs on its designated website. The Department will also continue DEL coverage for premiums, deductibles, co-payments, and coverage gaps (donut hole) in Medicare Part D coverage, as defined in Chapter 104, Section 4, to the extent that funds are available.

B. Co-Payments

1. For Retail Pharmacies

In the Basic benefit, the participant must pay a co-payment for services requested and rendered from retail pharmacies of 20% of the reimbursement amount as defined in Section 2.11, plus \$2 per prescription, not to exceed a 34-day supply for brand-name drugs, and up to and including a 90-day supply for generics.

2. For Mail Order Pharmacies

In the Basic benefit, the participant must pay a co-payment for services requested and rendered from mail order pharmacies of 20% plus \$2 of the reimbursement amount as defined in Section 2.11 for up to a 90-day supply of generic drugs or brand-name drugs.

2.06-2 **Supplemental Benefit**

A. Covered Drugs

The Supplemental benefit includes all drugs of those manufacturers that have entered a federal rebate agreement and a DEL rebate agreement that are not covered in the Basic benefit, including those used to treat illnesses and conditions not included in the Basic benefit ~~of those manufacturers that have~~

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2.06 **BENEFITS** (cont.)

~~entered a federal rebate agreement and a DEL rebate agreement, as set forth above. A prescription drug of a manufacturer that does not enter into an agreement pursuant to this paragraph is reimbursable only if the Department determines the prescription drug is essential.~~

B. Co-Payments

Under the Supplemental benefit, whether obtained through retail or mail order pharmacies, participants must pay 100% of the MaineCare prescription rate for brand-name drugs, as set forth in Subsection 2.11 of this Section, minus \$2 per prescription. For generic drugs, participants must pay the sum of \$2 plus 20% of the DEL prescription rate as set forth in Section 2.11.

2.06-3 **Catastrophic Benefit**

A. Covered Drugs

All drugs covered by either the Basic benefit or the Supplemental benefit are covered in the Catastrophic benefit.

B. Eligibility for the Catastrophic Benefit

Participants eligible for Medicare Part D are not eligible for catastrophic benefits under this Section.

Participants who are not Medicare Part D eligible are eligible for the Catastrophic benefit once that participant has paid total co-payments in the DEL benefit of at least \$1,000 between August 1 and July 31 of any year(s) in which the participant is eligible, provided that:

1. Only co-payments for those drugs that were included in the DEL Benefit on or before May 31, 2001 apply toward the Catastrophic benefit. A list of those drugs is available from the Department and on the Department's designated website; and
2. Only those co-payments that are tracked through the Department's automated pharmacy management information Point of Purchase System apply toward the Catastrophic benefit.

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2.06 **BENEFITS** (cont.)

C. Co-Payments

After the participant has paid a total of \$1,000 in co-payments as set forth in 2.06-3(B), the participant may purchase any drugs covered by either the Basic or Supplemental benefit by paying 20% of the reimbursement rate described in Section 2.11 until the next July 31.

2.06-4 **Prior Authorization (PA)**

A. Determining Which Drugs May Be Subject to Prior Authorization

The Department may require prior authorization for certain drugs in the DEL benefit as set forth in this sub-section.

In determining when prior authorization will be required, the Department will consider the recommendations of the DUR Committee. The determination to impose prior authorization will be based on the efficacy, safety, and net cost of any given drug and of the other drugs within the therapeutic category. The Department's determination of a drug's efficacy and safety shall be consistent with the standards set forth in (1) the peer-reviewed literature, and (2) the following compendia: the American Hospital Formulary Service Drug Information, the United States Pharmacopoeia-Drug Information, the DRUGDEX Information System, and American Medical Association Drug Evaluations. The Department's determination of a drug's net cost shall consider the pharmacy reimbursement amount as set forth at section 2.10 of this rule, as adjusted by any manufacturer rebates and or supplemental rebates to be paid to the Department for that drug. The Department may not consider net cost when imposing prior authorization unless it determines that the drug to be subject to prior authorization has no significant clinical or safety advantages over one or more alternative drugs, when used for a given purpose. The Department may also consider the indications for which the drug may be prescribed, where appropriate.

The Department may require prior authorization of any generic drug that has a net cost that is greater than the net cost of its brand-name version.

The Department, in consultation with the DUR Committee, may determine that the prior authorization requirement may be waived on a case-by-case basis for patients who are established on a drug that otherwise might be subject to prior authorization.

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2.06 **BENEFITS** (cont.)

B. Exemptions From Prior Authorization

The Department has the discretion to exempt providers and/or participants from prior authorization requirements. The Department may discontinue these PA compliance exemptions any time with written notice. Exemptions are as described in this Section:

1. Provider Exemptions from Prior Authorization

a. Three-Month PA Compliance Exemptions

Providers may receive a 3-month exemption from prior authorization requirements for certain categories of drugs when they demonstrate high compliance with the Department's PDL. The Department runs quarterly reports to identify providers who prescribe 95% or more of their prescriptions, within certain categories of drugs, in compliance with the PDL. When providers are thus identified, they may receive a 3-month exemption from PA requirements when prescribing drugs for participants within the identified drug categories. The Department will notify providers in writing which drug categories are included and what dates apply to the exemption.

b. Twelve-Month PA Compliance Exemptions

When providers have met all requirements for the 3-month compliance exemption described above, and have received that exemption for 3 out of 4 quarters of a year, the Department may grant a 1-year exemption for prior authorization requirements when prescribing drugs for participants within certain categories of drugs. The Department will notify providers in writing which drug categories are included and what dates apply to the exemption.

c. Exemptions for Specialty Providers

The Department, in consultation with the DUR Committee, and consistent with standards set forth in 2.06-4(A), may waive the prior authorization requirements for specific provider specialists on a drug-by-drug basis.

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BENEFITS (cont.)

2. Provider Exemptions from Prior Approval

a. Primary Insurance Exemptions from Prior Authorization

The Department may waive the prior authorization requirements for participants receiving non-preferred drugs when DEL or MaineCare is the secondary payer.

b. Other Special Exemptions from Prior Authorization for Participants

The Department, in consultation with the DUR Committee, and consistent with standards set forth in 2.06-4(A), may waive the prior authorization requirement for specific drugs or medical conditions, on a drug-by-drug basis for participants who have been established for at least 1 year on a drug that otherwise might be subject to prior authorization.

3. Open-Ended Participant Prior Approval

Participants may receive open-ended PAs for specific drugs after having been established on a non-preferred drug and meeting all other prior authorization requirements for at least 1 year. These open-ended PAs do not need to be renewed on an annual basis. These PAs may be issued after the Department determines that the participant's condition is stable, and will remain unchanged if continued on the specific drug. The Department reserves the right to review the PA status should a new and more efficacious alternative become available.

C. Process for Seeking Prior Authorization

When the Department requires prior authorization, the participant's physician must complete and submit a written form, including any required attachments, documenting the medical necessity of the prescribed drug. The Department may seek information such as documentation of other measures that have been attempted to correct the risk/condition, the timeframe in which those other measures were attempted, and the reason for failure. The prescriber is also required to submit documentation that other drugs in the same therapeutic category are contraindicated.

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BENEFITS (cont.)

The Department will notify prescribers of the drugs that are subject to prior authorization and will provide them with forms for requesting authorization setting forth the information needed to approve a request. The list of drugs requiring PA and forms will be available on a website designated by the Department.

The requesting prescriber must complete the form applicable to the drug for which prior authorization is sought. The prescriber must send the completed form to the Department or its designee, as instructed by the Department, by mail, fax or by hand delivery. During regular business days, the Department or its designee will respond to a completed request for prior authorization by fax, telephone or other telecommunications device within 24 hours of receipt.

In an emergency situation, including weekends, holidays, or any other time that the Department or its designee is not able to respond to a completed prior authorization request within 24 hours of receipt, the pharmacist is authorized to provide a one-time 96-hour supply of any prescribed drug that is a covered drug. The Department or its designee shall respond to a completed request under this subpart on the next regular business day. The provision of a 96-hour supply under this subpart does not relieve the prescriber of the obligation to complete and submit the prior authorization request form.

In the event that a prescriber fails to submit a completed form for a drug requiring prior authorization, the Department or its designee may authorize the pharmacy to dispense a one-time 34-day supply of the prescribed drug. The authorization of a 34-day supply under this provision does not relieve the prescriber of the obligation to complete and submit the prior authorization request form. If the prescriber has still failed to submit a completed prior authorization request by the end of the additional 34-day period, the Department will consider any refills of that prescription on a case-by-case basis. The Department may require a provider to redo the prior authorization process every 12 months, or sooner if the participant's medical condition or the prior authorization criteria change.

2.06-5

Preferred Drug List

A. General

In order to facilitate appropriate utilization, the Department will establish a list of covered drugs, ordered by therapeutic category. Within each therapeutic category, the Department may designate some or all drugs as preferred on the basis of efficacy,

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2.06 **BENEFITS** (cont.)

safety, and net cost. The Department's determination of a drug's efficacy and safety shall be consistent with the standards set forth in (1) the peer-reviewed literature, and (2) the following compendia: The American Hospital Formulary Service Drug Information, the United States Pharmacopoeia-Drug Information, the DRUGDEX Information System, and American Medical Association Drug Evaluations. The Department's determination of a drug's net cost shall consider the pharmacy reimbursement amount as set forth at Section 2.10 of this rule, as adjusted by any manufacturer rebates and or supplemental rebates to be paid to the Department for that drug. The Department may not consider net cost when imposing prior authorization unless it determines that the drug to be subject to prior authorization has no significant clinical or safety advantages over one or more alternative drugs, when used for a given purpose. This listing will be known as the Preferred Drug List or PDL.

In addition to the preferred/non-preferred designation, the PDL may include information such as generic name, strength/unit, National Drug Code identification number, and brand name.

All covered drugs, whether preferred or non-preferred, are available to any eligible participant for whom those drugs are medically necessary. Some drugs must have their medical necessity confirmed for a given participant through the prior authorization process before the Department will provide reimbursement.

B. Step Order

In addition to the preferred/non-preferred designations, the Department may assign some drugs on the PDL a further designation of preference within a therapeutic category. This further designation will be known as step order.

The step order is a means of reducing the need to obtain prior authorization. When a participant has been prescribed all drugs at a higher step(s) within a therapeutic category, the drug at the next lower step will automatically be reimbursed for that participant without requiring prior authorization. Only drugs prescribed to the participant since enrollment and reflected in the Department's automated pharmacy management information Point of Purchase System will be considered in applying the step order.

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LAST UPDATED 9/15/06

2.06 **BENEFITS (cont.)**

C. Notification

The Department will post the PDL on the Department's designated web site. The Department will also provide quarterly notification of the drugs selected for placement on the PDL, and any other changes in the PDL. The list will be provided upon request to participants and providers who do not have Internet access.

2.07 **DISPENSING PRACTICES**

Retail pharmacy providers may dispense up to a 34-day supply of brand name drugs and up to a 90-day supply of generic drugs.

Mail order pharmacies may only dispense up to 90-day supplies of generic or brand-name drugs. When refilling a prescription through mail order, refills may be provided only at a participant's request; mail order pharmacies may not automatically refill prescriptions for participants.

Providers dispensing prescriptions via telepharmacy must obtain approval from the Department. Providers must assure that participant counseling is available at the remote site from the dispensing provider or the provider delivering the prescription, and that only qualified staff, as defined by the Maine State Board of Pharmacy, deliver prescriptions.

2.08 **FINANCIAL PARTICIPATION (CO-PAYMENT)**

When the DEL Benefit level requires a co-payment, the Department requires each DEL participant to pay the co-payment for drugs, as set forth above. There are no exceptions. If the participant refuses to pay the co-payment, the pharmacy will deny the service.

2.09 **ELIGIBILITY CARD**

The Department of Health and Human Services issues an eligibility card to each eligible participant enrolled in the DEL Benefit. A participant must present the eligibility card to the participating pharmacy upon request.

2.10 **AMOUNT AND DURATION OF BENEFITS**

The Department may stop reimbursing for covered drugs if, in any fiscal year, all the funds appropriated for DEL have been expended. When necessary, the Department will provide participants and participating pharmacies with prior notice of the date upon which reimbursement will cease.

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2.11 REIMBURSEMENT

The Department will reimburse participating pharmacies only for drugs that are covered drugs as set forth above.

The DEL Benefit is the payor of last resort. If the participant has another prescription drug coverage plan, that plan must be billed first.

A. The Department may establish the Maine Maximum Allowable Cost (MMAC) for covered drugs, considering the following factors:

1. Multiple manufacturers;
2. Broad wholesale price span;
3. Availability of drugs to retailers at the selected cost;
4. High volume of utilization; and
5. Bioequivalence or interchangeability.

B. For retail pharmacies the amount of reimbursement will be the lowest of the following:

1. For Generic Drugs

- a. The usual and customary charge; or
- b. The Maine Maximum Allowable Cost plus a \$2.35 professional fee; or
- c. The Average Wholesale Price minus 14% plus a \$2.35 professional fee; or
- d. The State Upper Limit (250% of Average Manufacturer's Cost for multi-source generic drugs) plus a \$2.35 professional fee.

2. For Brand-Name Drugs

- a. The usual and customary charge; or
- b. The Average Wholesale Price minus 15% plus a \$2.35 professional fee.

C. For mail order pharmacies, the amount of reimbursement will be the lowest of the following:

1. For Generic Drugs

- a. The usual and customary charge; or

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2.11 **REIMBURSEMENT** (cont.)

- b. The Average Wholesale Price minus 60% plus \$1.00 professional fee except as otherwise noted below, or
 - c. The Maine Maximum Allowable Cost plus \$1.00 professional fee.
- 2. For Brand-Name Drugs
 - a. The usual and customary charge; or
 - b. The Average Wholesale Price minus 20% plus \$1.00 professional fee.

2.12 **PHARMACY RURAL DISPENSING FEE ADJUSTMENT**

The Department will pay a supplemental dispensing fee for prescriptions provided to members residing in rural areas in an attempt to assure continuing access to prescription services for these members. The rural dispensing fee will range from 55¢ to 65¢ per prescription dispensed to rural members, and will change on a quarterly basis to reflect the prior quarter's number of prescriptions filled. The Department will distribute the rural dispensing fee adjustment retrospectively on a quarterly basis. The Department will calculate the quarterly adjustment for each pharmacy by taking that quarter's total allotment and dividing the total allotment for the quarter by the number of prescriptions filled for rural members in the quarter. The Department will then group these by pharmacy and distribute in the quarter following. Pharmacies will be notified on a quarterly basis on the Department's designated website the amount of the adjustment for the quarter.

Rural members will be defined using a standard and federally recognized definition of rural using Metropolitan Statistical Area (MSA) designations. The Department will determine MSA/Non-MSA designation based on the zip code of the member's residence.

MAINE RETAIL PHARMACY PROVIDER INCENTIVE PAYMENT

~~The Maine Retail Pharmacy Provider Incentive Payment will recognize pharmacies that provide quality pharmacy care to DEL participants living in rural areas. A retail pharmacy must meet at least one of the following conditions to be eligible for this payment: The retail pharmacy must be: 1) the sole pharmacy provider in a community, as determined by zip code of the pharmacy's location; or 2) an independent pharmacy (an entity or individual with an ownership interest in fewer than 4 pharmacy locations); or 3) a retail pharmacy serving participants in supervised settings outside their immediate area (as determined by zip code) where 50% or more of the participants are outside the pharmacy's immediate area, and at least 100 prescriptions are dispensed per quarter for participants outside its immediate area.~~

~~The Department will calculate the incentive payment by creating a percentile score based on criteria described below. Each pharmacy's practices will be compared to other pharmacies and then given an overall ranking. Each eligible pharmacy will be given this performance based percentage using factors described below. The performance based percentage will be multiplied by a factor of the amount of prescriptions reimbursed by the pharmacy in the quarter being~~

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~~allocated, such that no pharmacy receives an incentive payment that exceeds 3% of their DEL pharmacy reimbursement in that quarter. The Department will calculate the incentive payment on a quarterly basis and send payments to eligible pharmacies within 30 days following the end of the quarter. The following describes factors considered to calculate the incentive:~~

- ~~1. Access for DEL participants as measured by percentage of unduplicated DEL participants served (50% weight)~~
- ~~2. Pharmacies filling a minimum of 25 compounding prescriptions for DEL participants per month (10% weight)~~
- ~~3. Generic drug utilization rate (5% weight)~~
- ~~4. PDL compliance (10% weight)~~
- ~~5. Ratios of prior authorizations (PA's) submitted to claims paid (5% weight)~~
- ~~6. Ratio of emergency claims paid to claims paid (10% weight)~~
- ~~7. Other third party payer coverage dollars collected (5% weight)~~
- ~~8. Length of time participating in the Maine Rx Plus and Maine Drugs for the Elderly Benefit (5% weight)~~

2.13 **APPEALS**

Each participant has the right to an administrative hearing to appeal any decision by the Department that adversely affects that participant's benefit. These appeal rights are set forth in Chapter 104, Section 1.

2.14 **BILLING INSTRUCTIONS**

Participating pharmacies must bill in accordance with the Department's billing instructions set forth in the pharmacy's MaineCare agreement.

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3.01 **AUTHORITY**

The Maine Rx Plus Benefit is authorized by, and these regulations are issued under, the authority of 22 MRSA § 2681(14). The Commissioner of the Department of Health and Human Services has delegated the responsibility for administration of the Benefit to the ~~Bureau of Medical~~Office of MaineCare Services.

3.02 **DEFINITIONS**

3.02-1 **Average Wholesale Price** means the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file.

3.02-2 **Brand Name Drug** is defined as a single-source drug, a cross-licensed drug, or an innovator drug.

3.02-3 **Covered Drugs** means drugs that are on the MaineCare Preferred Drug List established by the Department pursuant to its authority to operate the MaineCare program, and revised from time to time, as published on the Department's designated website.

3.02-4 **Department** means Department of Health and Human Services.

3.02-5 **Generic Drugs** are drugs other than those defined as brand-name drugs.

3.02-6 **Initial Discounted Price** for a drug means the amount that MaineCare reimburses pharmacies for any given drug pursuant to Section 80 of the MaineCare Benefits Manual.

3.02-7 **Labeler** means an entity or person who receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the Federal Food and Drug Administration under 21 CFR §207.20.

3.02-8 **Mail Order Pharmacy** is a pharmacy provider that dispenses prescription medications by U.S. mail or private carrier. Mail order pharmacies must have a NABP (National Association of Boards of Pharmacy) provider number uniquely identifying the provider as a mail order pharmacy for purposes of billing. Mail order pharmacies must be licensed by the Maine Board of Pharmacy, enrolled as Medicare and MaineCare providers, and be operating under contract with the Department. Mail order pharmacies must dispense prescription medications from within the United States. Mail order pharmacies must process claims through the State's electronic claims processing system to the standards required by the Department.

3.02-9 **Metropolitan Statistical Area (MSA)** is a federal standardized designation using postal zip codes to define rural areas. The Department will define rural by applying MSA/Non-MSA designation to the zip code of the member's residence.

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3.02 **DEFINITIONS** (cont.)

3.02-~~9~~10 **National Drug Code (NDC)** is the identifying number for a drug maintained by the Food and Drug Administration.

3.02-~~40~~11 **Participating Pharmacy** means a pharmacy located in Maine, or another business licensed to dispense prescription drugs in this State, that participates in Maine Rx Plus, and that has signed a Maine Rx Plus provider agreement.

3.02-~~44~~12 **Retail pharmacy** is a pharmacy that possesses a valid outpatient pharmacy license issued by the Board of Pharmacy, accepts Medicare assignment, and which serves Maine Rx Plus participants.

3.02-~~42~~13 **Secondary Discounted Price** means the initial discounted price minus any further discounts paid for out of the Maine Rx Plus dedicated fund.

3.02-~~43~~14 **Telepharmacy** is a method of delivering prescriptions dispensed by a pharmacist to a remote site. Pharmacies using telepharmacy delivery of prescriptions must follow all applicable State and Federal regulations and Maine State Board of Pharmacy rules, including using staff qualified to deliver prescriptions through telepharmacy.

3.03 **BENEFIT ELIGIBILITY**

Any person whose family income is less than or equal to 350% of the federal poverty level is eligible for the Maine Rx Plus Benefit. This is referred to as “financial eligibility.” Applicants will remain eligible for one year beginning on the date determined eligible and must reapply annually.

In addition, any person who incurs unreimbursed expenses for prescription drugs equaling 5% or more of family income, or who incurs unreimbursed expenses for all medical care equaling 15% or more of family income, is eligible for the remainder of the eligibility period. This is referred to as “spend down eligibility.”

The Department will use the following processes to determine eligibility:

A. Determination of Financial Eligibility

The ~~Bureau of Family Independence (BFI)~~Office of Integrated Access and Support (OIAS) will determine family income as set forth at 10-144 C.M.R. Chapter 332, MaineCare Eligibility Manual. If the family income as determined by BFI is equal to or less than 350% of the federal poverty level, the applicant is financially eligible for Maine Rx Plus Benefits.

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3.03 **BENEFIT ELIGIBILITY** (cont.)

B. Determination of Spend Down Eligibility

If applicants do not meet financial eligibility as determined by ~~BFI~~ FI O I A S, they may request that the Department consider eligible expenses incurred by the household during the six months prior to application. This six-month period is the medical spend down eligibility period. The Department will use income information prorated for this time period to determine the percentage of expenses incurred during the medical spend down eligibility period. If the applicant's unreimbursed expenses for prescription drugs are equal to 5% or more of family income, or unreimbursed expenses for medical care are equal to 15% or more of family income, the applicant is eligible for Maine Rx Plus on the basis of the spend down.

To be considered for spend down eligibility applicants must submit receipts or bills for unreimbursed prescription drug expenses and/or medical expenses to the Maine Rx Plus Spend Down, Department of Health and Human Services, 11 State House Station, Augusta Maine, 04333-0011. Applicants may submit a signed statement of incurred expenses for those expenses for which a receipt has been lost. If found eligible due to medical spend down, applicants will remain eligible for one year from the date application is made.

All documented, unreimbursed medical and prescription drug expenses incurred by the applicant or family member shall be considered in the spend down determination, except the following:

1. Any costs incurred and paid prior to the medical spend down period; or
2. Any medical costs paid by any third party, including an insurance carrier or a state or federal government benefits program; or
3. Medical costs paid by others for which the individual has no obligation to repay.

The Department will notify applicants within 30 days of receipt of documented prescription and medical expenses whether or not they are eligible for Maine Rx Plus.

3.04 **ENROLLMENT CARD**

The Department or its authorized agent will issue an eligibility card to each participant enrolled in the Maine Rx Plus Benefit. The Department will issue permanent cards by mail.

3.05 **APPEALS**

Each participant has the right to an administrative hearing to appeal any decision by the Department that adversely affects that participant's Benefit. These appeal rights are set forth in Chapter 104, Section 1, Maine State Services Manual, Administrative Policies and Procedures.

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3.06 PHARMACY PARTICIPATION

- A. Only participating pharmacies may submit claims for payment under the Maine Rx Plus Benefit. To become a participating pharmacy a pharmacy must meet all of the following criteria:
 - 1. Comply with all provider and administrative process requirements set forth in Chapter 104, Section 1;
 - 2. Be enrolled as a MaineCare pharmacy provider; and
 - 3. Execute a Maine Rx Plus Provider Agreement with the Department.
- B. The Department will not charge a participating pharmacy for submitting claims or participating in this Benefit.
- C. The participating pharmacy may decline to dispense any prescription that appears to be improperly executed and/or which, in the professional judgment of the pharmacist, is unsafe as presented, or may be harmful if not monitored.

3.07 DISPENSING PRACTICES

Dispensing practices must be in accordance with the best medical, pharmaceutical and economical practice.

Retail pharmacy providers may dispense up to a 34-day supply of brand name drugs and up to a 90-day supply of generic drugs. Mail order pharmacies may only dispense up to 90-day supplies of generic or brand-name drugs. When refilling a prescription through mail order, refills may be provided only at a participant's request; mail order pharmacies may not automatically refill prescriptions for participants.

Providers dispensing prescriptions via telepharmacy must obtain approval from the Department. Providers must assure that participant counseling is available at the remote site from the dispensing provider or the provider delivering the prescription, and that only qualified staff, as defined by the Maine State Board of Pharmacy, deliver prescriptions.

The Department may issue a request for proposals from labelers or manufacturers and issue a contract for the provision of generic drugs. Participant providers may be required by the Department to obtain a generic drug from labelers or manufacturers with which the Department contracts. The Department will notify providers and give instructions for compliance with this provision.

3.08 TERMINATION OF PHARMACY PARTICIPATION

A participating pharmacy may terminate participation in the Maine Rx Plus Benefit at any time by following the termination provisions set forth in the Maine Rx Plus Provider Agreement.

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3.09 **COVERED DRUGS**

There is no maximum frequency, number, or cost of the prescriptions filled for an individual participant. When drugs are obtained through a mail order pharmacy, participants may obtain only up to a 90-day supply.

A. Covered Drugs

Under the Maine Rx Plus Benefit, the Department will cover and reimburse only for drugs that are both prescribed by an authorized prescriber and listed as preferred in the MaineCare preferred drug list (PDL) established pursuant to Chapter II, Section 80, Pharmacy Services of the MaineCare Benefits Manual.

B. Drug Benefit

Initial Discount. Until October 1, 2004 Maine Rx Plus participants will pay the initial discounted price (as defined above) for all covered drugs.

Secondary Discount. After October 1, 2004 the Department will further reduce the cost of some covered drugs with a secondary discount. A drug will receive a secondary discount if the manufacturer or labeler of that drug has entered into a Maine Rx Plus rebate agreement with the Department. The amount of the Secondary Discount will be an average of all the rebates the Department has negotiated for Maine Rx Plus, after deducting certain administrative expenses incurred by the Department.

Maine Rx Plus participants must pay the entire initial discounted price or secondary discounted price, whichever is in effect. There are no exceptions. If the participant refuses to pay the entire discounted price, the pharmacy will deny the service.

C. Maine Rx Plus Rebate Agreements

The Department will negotiate with manufacturers of covered drugs to obtain rebates for the Maine Rx Plus Benefit. As consideration for such rebates, the Department will offer manufacturers or labelers that are willing to pay rebates preferred status within the Maine Rx Plus list of covered drugs. The drugs of manufacturers or labelers that do not agree to pay rebates will remain covered drugs in Maine Rx Plus but will not be given the preferred designation in Maine Rx Plus.

The rebate agreements will require each pharmaceutical manufacturer or labeler to make quarterly rebate payments to the Department for the total number of dosage units of each form and strength of a prescription drug that the Department reports as reimbursed to participating pharmacies. Such payments shall be due thirty (30) days following the date the manufacturer receives utilization data from the Department summarizing the number of dosage units of drugs during the period for which payment is due.

When the pharmaceutical manufacturer or labeler receives the pharmacy reimbursement data, the pharmaceutical manufacturer or labeler shall calculate the quarterly payment. The Department may, at its expense, hire a mutually agreed upon independent auditor to verify the calculation and payment.

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3.09 **COVERED DRUGS** (cont.)

In the event that an independent audit discovers a discrepancy between the pharmaceutical manufacturer's or labeler's calculation and the independent auditor's calculation that benefits the Department, the pharmaceutical manufacturer or labeler shall justify its calculation or make payment to the Department for any additional amount due. The pharmaceutical manufacturer or labeler may, at its expense, hire a mutually agreed upon independent auditor to verify the accuracy of the utilization data provided by the Department.

In the event that a discrepancy is discovered that benefits the pharmaceutical manufacturer or labeler, the Department shall justify its data or refund any excess payment to the pharmaceutical manufacturer or labeler.

3.10 **REIMBURSEMENT**

A. Eligible Claims

Maine Rx Plus provides benefits for discounted drugs only when participants do not have coverage under a comparable or superior prescription drug plan. Participating pharmacies must always determine the existence of and seek reimbursement from an individual's comparable or superior prescription drug benefit prior to submitting claims to the Maine Rx Plus Benefit.

B. Amount of Reimbursement for Retail Pharmacies

For each eligible prescription filled, the participating retail pharmacy will be reimbursed a \$3.35 dispensing fee plus the lowest of the following:

1. Federal Upper Limits (FUL) as defined in Chapter II, Section 80, Pharmacy Services, of the MaineCare Benefits Manual (MBM); or
2. Maine Maximum Allowable Cost (MMAC) as defined in Chapter II, Section 80, Pharmacy Services, of the MBM; or
3. Average Wholesale Price minus 13%; or
4. The participating pharmacy's Usual and Customary (U & C) Price; or
5. The State Upper Limit (250% of Average Manufacturer's Cost for multi-source generic drugs) plus a \$2.35 professional fee.

The Department will not pay any costs for payments for which the participant is responsible.

The Department will also reimburse the participating pharmacy in the amount of any applicable secondary discount, which the pharmacy will pass along in full as an additional discount to the Maine Rx Plus participant

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3.10 **REIMBURSEMENT** (cont.)

C. Amount of Reimbursement for Mail Order Pharmacies

For mail order pharmacies, the amount of reimbursement will be the lowest of the following:

1. For Generic Drugs

The reimbursement rate for covered generic drugs obtained through mail order pharmacies shall be the lowest of the following:

- a. The Usual and Customary Price; or
- b. The Average Wholesale Price minus 60% plus \$1.00 professional fee except as otherwise noted below, or
- c. The Maine Maximum Allowable cost plus \$1.00 professional fee except as noted in Section 3.10.

2. For Brand Name Drugs

The reimbursement rate for covered brand name drugs obtained through mail order pharmacies shall be the lowest of the following:

- a. The Usual and Customary Price; or
- b. The Average Wholesale Price minus 20% plus \$1.00 professional fee except as otherwise noted below, or
- c. The Maine Maximum Allowable Cost plus \$1.00 professional fee except as noted in Section 3.10.

D. Billing Instructions

Participating pharmacies must bill in accordance with the Department's billing instructions set forth in the pharmacy's MaineCare agreement. A pharmacy licensed both as a retail and mail order pharmacy must bill for mail order services at the mail order rate.

3.11 PHARMACY RURAL DISPENSING FEE ADJUSTMENT

The Department will pay a supplemental dispensing fee for prescriptions provided to members residing in rural areas in an attempt to assure continuing access to prescription services for these members. The rural dispensing fee will range from 55¢ to 65¢ per prescription dispensed to rural members, and will change on a quarterly basis to reflect the prior quarter's number of prescriptions filled. The Department will distribute the rural dispensing fee adjustment retrospectively on a quarterly basis. The Department will

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3.11 PHARMACY RURAL DISPENDING FEE ADJUSTMENT (cont.)

calculate the quarterly adjustment for each pharmacy by taking that quarter's total allotment and dividing the total allotment for the quarter by the number of prescriptions filled for rural members in the quarter. The Department will then group these by pharmacy and distribute in the quarter following. Pharmacies will be notified on a quarterly basis on the Department's designated website the amount of the adjustment for the quarter.

Rural members will be defined using a standard and federally recognized definition of rural using Metropolitan Statistical Area (MSA) designations. The Department will determine MSA/Non-MSA designation based on the zip code of the member's residence.

MAINE RETAIL PHARMACY PROVIDER INCENTIVE PAYMENT

The Maine Retail Pharmacy Provider Incentive Payment will recognize pharmacies that provide quality pharmacy care to Maine Rx Plus participants living in rural areas. A retail pharmacy must meet at least one of the following three conditions to be eligible for this payment: The retail pharmacy must be: 1) the sole pharmacy provider in a community, as determined by zip code of the pharmacy's location; or 2) an independent pharmacy (an entity or individual with an ownership interest in fewer than 4 pharmacy locations); or 3) a retail pharmacy serving participants in supervised settings outside their immediate area (as determined by zip code) where 50% or more of the participants are outside the pharmacy's immediate area, and at least 100 prescriptions are dispensed per quarter for participants outside its immediate area..

The Department will calculate the incentive payment by creating a score based on criteria described below. Each pharmacy's practices will be compared to other pharmacies and then given an overall ranking. Each eligible pharmacy will be given this performance based percentage using factors described below. The performance based percentage will be multiplied by a factor of the amount of prescriptions reimbursed by the pharmacy in the quarter being allocated, such that no pharmacy receives an incentive payment that exceeds 3% of their Maine Rx Plus pharmacy reimbursement in that quarter. The Department will calculate the incentive payment on a quarterly basis and send payments to eligible pharmacies within 30 days following the end of the quarter. The following describes how which factors are considered to calculate the incentive:

1. Access for Maine Rx Plus participants as measured by percentage of unduplicated Maine Rx Plus participants served (50% weight)
2. Pharmacies filling a minimum of 25 compounding prescriptions for Maine Rx Plus participants per month (10% weight)
3. Generic drug utilization rate (5% weight)
4. PDL compliance (10% weight)
5. Ratios of prior authorizations (PA's) submitted to claims paid (5% weight)
6. Ratio of emergency claims paid to claims paid (10% weight)
7. Other third party payer coverage dollars collected (5% weight)

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~~8. Length of time participating in Maine Rx Plus and DEL benefit (5% weight)~~

3.12 RECORDS FOR AUDIT PURPOSES

The participating pharmacy must agree to submit to an audit. The Department of Health and Human Services or its designated agent will conduct the audit using records and transactions involving the dispensing of any and all prescription drugs under the Maine Rx Plus Benefit. The participating pharmacy must also agree to furnish for review all materials and information regarding payment, including actual prescriptions, invoices for drug purchases, other appropriate documents, and any additional information that may be required by those authorized to determine compliance with this policy.

3.13 FRAUD OR ABUSE

- A. The State of Maine administers the Maine Rx Plus Benefit and participating pharmacies and participants are subject to Maine statutes pertaining to fraud.
- B. All provisions relating to fraud and abuse and related sanctions outlined in Chapter 104, Section 1 of the Maine State Services Manual are applicable.
- C. Fraud includes, but is not limited to an eligible participant allowing, assisting or conspiring with an ineligible individual to obtain drugs under this Benefit.

3.14 CONFIDENTIALITY

The Department follows/subscribes to all State or Federal law, rules or regulations related to confidentiality, as further detailed in Chapter 104, Section 1.

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SECTION 4

MAINE PART D WRAP BENEFITS

ESTABLISHED 1/1/06

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4.01 **AUTHORITY**

This benefit is authorized by, and these regulations are issued under, the authority of 22 M.R.S.A. § 254-D. The Commissioner of the Department of Health and Human Services has delegated the responsibility for administration of the benefit to the Office of MaineCare Services.

4.02 **DEFINITIONS**

- 4.02-1 **Authorized Representative** refers to the Department's authority pursuant to 22 M.R.S.A. § 254-D to enroll and reenroll participants into a Medicare Part D plan, apply for Medicare Part D benefits and subsidies on their behalf, and at the Department's discretion, file exceptions and appeals on their behalf. The Department may also identify a designee for this function.
- 4.02-2 **Beneficiary** under Medicare Part D means a person who is eligible for benefits and enrolled in a Medicare Part D plan.
- 4.02-3 **Brand Name Drug** is defined as a single-source drug, a cross-licensed drug, or an innovator drug.
- 4.02-4 **Covered Drug** is a drug for which the Department reimburses under this benefit. See Subsection 4.05 and Appendix A of this Section.
- 4.02-5 **Generic Drugs** are drugs other than those defined as brand-name drugs.
- 4.02-6 **Mail Order Pharmacy** is a pharmacy provider that dispenses prescription medications by U.S. mail or private carrier. Mail order pharmacies must have a NABP (National Association of Boards of Pharmacy) provider number uniquely identifying the provider as a mail order pharmacy for purposes of billing. Mail order pharmacies must be licensed by the Maine Board of Pharmacy, enrolled as Medicare and MaineCare providers, and be operating under contract with the Department. Mail order pharmacies must dispense prescription medications from within the United States. Mail order pharmacies must process claims through the State's electronic claims processing system to the standards required by the Department.
- 4.02-7 **MaineCare Benefits Manual (MBM)** is the MaineCare policy set forth in Department of Health and Human Services, 10-144, Chapter 101, MaineCare Benefits Manual.
- 4.02-8 **MaineCare Member** means a person who receives benefits under the MaineCare Program.
- 4.02-9 **Medicare Part D** means the prescription drug benefit program provided under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173.

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4.02

DEFINITIONS (cont.)

- 4.02-10 **Medicare Part D Excluded Drugs** are those drugs not covered by MedicarePart D pursuant to Title XIX, Section 1927 of the Social Security Act [42 U.S.C. § 1396r-8], for which the Department will continue to reimburse if otherwise covered under this Section. The Department will post a complete list of these covered drugs on its designated website, and the list will include but not be limited to the following categories of drugs: over the counter drugs, certain weight loss drugs, agents when used for the symptomatic treatment of cough and cold, vitamins/minerals, outpatient drugs for which associated tests or monitoring must be purchased exclusively from manufacturers, barbiturates, and benzodiazepins.
- 4.02-11 **Medicare Savings Program Eligible** refers to a participant who is also eligible for MaineCare through the Medicare Buy-In Program, as defined in the MaineCare Eligibility Manual (MEM) and designated as QMB, SLMB, or QI.
- 4.02-12 **National Drug Code (NDC)** is a universal drug coding system for human drugs established by the Federal Food and Drug Administration, as set forth in 21 C.F.R § 207. The FDA assigns each drug a unique identification number specifying the labeler/vendor, product, and package.
- 4.02-13 **Non-Preferred Drugs** are covered drugs that are not preferred drugs.
- 4.02-14 **OBRA 90** is the Omnibus Budget Reconciliation Act of 1990 as amended.
- 4.02-15 **Over-The-Counter Drug (OTC)** is a drug that can be purchased without a prescription.
- 4.02-16 **Participant** is an individual who is eligible for and is receiving this benefit.
- 4.02-17 **Pharmacy Provider** is a corporation, association, partnership, or individual that either provides pharmacy services pursuant to a provider agreement with MaineCare or is related by ownership or control to an entity that provides MaineCare or DEL Benefit services, and is also a Medicare pharmacy provider.
- 4.02-18 **Preferred Drugs** are covered drugs that are clinically efficacious and which have a lower therapeutic category as determined by the Department after reviewing the recommendation of the Drug Utilization Review Committee.
- 4.02-19 **Preferred Drug List (PDL)** is a listing of covered drugs setting forth such information as their status as preferred or non-preferred, whether prior authorization may be required, step order, and any other information as determined by the Department to be helpful to participants, pharmacists, prescribers and other interested parties. This benefit utilizes the PDL referenced in Chapter 104, Section 2, Drugs for the Elderly.

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4.02 **DEFINITIONS** (cont.)

- 4.02-20 **Prescription Drug Plan (PDP)** is a Medicare Part D plan provider that is also an approved contractor under contract with the DHHS.
- 4.02.21 **Retail Pharmacy** is a pharmacy that possesses a valid outpatient pharmacy license issued by the Board of Pharmacy, accepts Medicare assignment, and which serves DEL participants.
- 4.02-22 **Therapeutic Category** is a grouping of drugs by comparable therapeutic effect, as determined by the Department.
- 4.02-23 **Usual & Customary Charge** is the amount a pharmacy charges to individuals for prescription drugs for which those individuals do not have insurance coverage.
- 4.02-24 **Wrap Benefits** are benefits offered through this Section that may include assistance with co-payments, deductibles, premiums and gaps in coverage. Wrap benefits vary for some members, and details of the benefit are outlined in the table in Appendix A.

4.03 **ELIGIBILITY**

An individual is eligible to receive services as set forth in this Section if he or she meets the eligibility requirements established in 10-144 C.M.R. Chapter 333, and adheres to the additional requirements outlined below. Some participants may have restrictions on the type and amount of benefits they are eligible to receive under this Section.

DEL participants enrolled in Medicare who are not MaineCare members must be enrolled in an approved PDP that is under contract with the Department in order to be eligible for wrap benefits. The Department will enter enrolled participants into its electronic database. Entry into the Department's electronic database may occur in one of two ways:

1. Auto-enrollment whereby the Department automatically enrolls the participant into an approved PDP and enters the participant into the Department's database; or
2. Self-enrollment by the participant into an approved PDP. Participants who self enroll must communicate their enrollment to the Department, at which time the Department will confirm the information and enter the participant into its database. Providers should inform participants to call the Department's toll free help line at 1-866-796-2463 to report self-enrollment.

DEL members who are MaineCare members are eligible to receive wrap benefits with any Medicare-approved PDP.

4.04 **PARTICIPATION IN MEDICARE PART D WRAP BENEFITS**

Participants must exhaust other pharmacy benefits including Medicare Part D and MaineCare before using benefits under this Section.

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4.04-1 Authorized Representative

The Department may act as an authorized representative for or appoint a designee to act as an authorized representative for participants who are eligible for Medicare Part D.

As an authorized representative, the Department may:

- a. deem eligible and enroll and reenroll participants in a Medicare Part D plan;
- b. apply for Medicare Part D benefits and subsidies on behalf of enrollees;
- c. establish rules by which enrollees may opt out of participation in Medicare Part D; and
- d. at its discretion, file exceptions and appeals pertaining to Medicare Part D eligibility or benefits on behalf of enrollees.

4.04-2 Coverage of Drugs Excluded from Coverage Under Medicare Part D

For participants who are eligible for Medicare Part D, the Department may provide coverage of drugs excluded by Medicare Part D to the same extent that coverage is available to participants who are not eligible for Medicare Part D.

4.05 **BENEFITS**

As detailed in Chapter 104, Section 2, the DEL benefit is limited to drugs of manufacturers that have both a valid rebate agreement with the federal government pursuant to 42 U.S.C. § 1396r-8 and a DEL Rebate Agreement. The Maine Part D Wrap Benefit additionally allows coverage of drugs of manufacturers that may not have both a valid DEL and federal rebate agreement. Drugs may be subject to prior authorization and the step order as set forth in Chapter 104, Section 2. The Department may refuse coverage for a drug when the prescriber cannot demonstrate medical necessity.

4.05-1 Covered Benefits

See the chart in Appendix A for a summary of Covered Benefits under this Section.

4.05-2 Prior Authorization (PA)

The Department may require prior authorization for certain drugs in this benefit, and follows guidelines as set forth in Chapter 104, Section 2.

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4.05 **BENEFITS (cont.)**

4.05-3 Preferred Drug List

In order to facilitate appropriate utilization, the Department utilizes the Preferred Drug List as detailed in Chapter 104, Section 2.

4.06 **DISPENSING PRACTICES**

Retail pharmacy providers may dispense up to a 34-day supply of brand name drugs and up to a 90-day supply of generic drugs.

Drugs must be dispensed according to guidelines detailed in Chapter 104, Section 2.

4.07 **FINANCIAL PARTICIPATION (CO-PAYMENT)**

The Department requires each participant to pay a co-payment for drugs, as set forth in the chart in Appendix A. There are no exceptions. If the participant refuses to pay the co-payment, the pharmacy will deny the service.

4.08 **ELIGIBILITY LETTER**

The Department of Health and Human Services issues an eligibility card to each eligible participant enrolled in this benefit. A participant must present the eligibility card to the participating pharmacy upon request.

4.09 **AMOUNT AND DURATION OF BENEFITS**

The Department may stop reimbursing for covered drugs if, in any fiscal year, all the funds appropriated for this benefit have been expended. The Department will provide participants and participating pharmacies with prior notice of the date upon which reimbursement will cease.

4.10 **REIMBURSEMENT**

The Department will reimburse participating pharmacies only for drugs that are covered drugs as set forth in MaineCare Benefits Manual, Chapter 101, Chapter II, Section 80, Pharmacy Services, or in Maine State Services Manual, Chapter 104, Section 2, Drugs for the Elderly Benefit. This benefit is the payor of last resort. If the participant has another prescription drug coverage plan, that plan must be billed first.

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4.11 **APPEALS**

Each participant has the right to an administrative hearing to appeal any decision by the Department that adversely affects that participant's benefit. These appeal rights are set forth in Chapter 104, Section 1.

4.12 **BILLING INSTRUCTIONS**

Participating pharmacies must bill in accordance with the Department's billing instructions set forth in the pharmacy's MaineCare agreement.

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Appendix A- MAINE PART D WRAP BENEFITS COVERAGE CHART

Eligibility Group	Co-Payment	Premiums	Deductible	Gap	Part D Excluded Drugs*
Dual Eligibles Residing in Nursing Facilities	N/A	N/A	N/A	N/A	Covered as reimbursed under MaineCare Benefits Manual, Chapter II, Section 80 Pharmacy Services
Dual Eligibles residing in Assisted Living and Level I, II, III and IV PNMI Eligibles (as reimbursed under MaineCare Benefits Manual, Chapter III, Appendices C and F, Section 97, Private Non-Medical Institution Services), or who are co-pay exempt under Chapter 1, Section 1.09-2 of the MaineCare Benefits Manual.	100% of all co-payments	N/A	N/A	N/A	Covered as reimbursed under MaineCare Benefits Manual, Chapter II, Section 80 Pharmacy Services
All other Dual Eligibles	50% of the cost of Brand Name drugs with a cap of \$10 per prescription, and 100% of the cost of generics up to \$2.15.	N/A	N/A	N/A	Covered as reimbursed under MaineCare Benefits Manual, Chapter II, Section 80 Pharmacy Services
Medicare Savings Program DEL Eligibles (QMB, SLMB, QI)	50% of the cost of Brand Name drugs with a cap of \$10 per prescription, and up to \$2.15 per generic.	N/A	N/A	N/A	Covered as paid under Chapter 104, Section 2, DEL Policy
DEL members eligible for Medicare Part D	50% of the cost of Brand Name drugs with a cap of \$10 per prescription, and up to \$2.15 per generic.	100% of Part D Premiums	50% of the Part D deductible	Members will have co-pay of 20% plus \$2.	Covered as paid under Chapter 104 DEL Policy

* Please see the following website for a list of covered Part D excluded drugs: www.maineicarepdl.org (under “General Pharmacy Info”)